



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,225	12/18/2001	Wolff M. Kirsch	LOMAU.142A	3475

20995 7590 03/29/2004

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
----------	--------------

3761

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,225

Applicant(s)

KIRSCH, WOLFF M.

Examiner

Kim M. Lewis

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/22/02, 3/24/02, 7/8/02 and 1/13/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5.7.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

1. The preliminary amendment filed on 3/22/02 has been received and made of record in the application file wrapper. As requested, the specification has been amended.

Revocation of Power of Attorney

2. The Revocation of Power of Attorney papers filed 3/24/02 have been received and made of record in the application file wrapper.

Information Disclosure Statement

3. The information disclosure statements filed 7/8/02 and 1/13/03 have been received and made of record in the application file wrapper. Note the acknowledged PTO-1449 forms enclosed herewith.

Drawings

4. The drawings were received on 10/1/02. These drawings are approved by the examiner.

Specification

5. The abstract of the disclosure is objected to because "provides a" should read –

provides a --. Correction is required. See MPEP § 608.01(b).

6. The disclosure is objected to because of the following informalities:

Page 3, line 10, "provides a" should read --provides a--; and

Page 4, line 9, the brief description of Fig. 3A appears to be incorrect. The figure shows a wound opening and the surrounding skin, note the device and the opening therein. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 10, the claim is indefinite in that the examiner is unclear as to whether the applicant intends to claim a combination device comprising the wound sealing adhesive since in claim 1, the wound sealing adhesive is not positively recited and in claim 10, the applicant further limit the wound sealing adhesive.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3761

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 5, 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,616,642 ("Martin et al.").

As regards claims 1, 7 and 8, Martin et al. disclose a surgical drape for caesarean section, which functions as a wound approximation device. The drape comprises an opening (fenestration 13) and is constructed from vinyl chloride film sheet, which according to the applicant in his disclosure, does not form a strong bond with a wound-sealing adhesive used to seal a wound. Additionally, the drape comprises a pressure sensitive adhesive.

As regards claim 5, the portion of the resilient sheet of Martin et al. adjacent the opening and opposite the side of the resilient sheet to be placed against the skin comprises vinyl.

As regards claim 10, the applicants fail to positively recite the wound sealing adhesive. However, the applicant should note that wound sealing adhesive commonly comprises cyanoacrylate, note for example, U.S. Patent No. 4,057,535.

11. Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,668,050 ("Donnelly").

As regards claims 1, 2, 4 and 6, Donnelly discloses a surgical drape, which approximates a wound, thereby being a wound approximation device. The device comprises a resilient elastomeric polyurethane sheet (12), wherein a portion of the

Art Unit: 3761

resilient sheet (vinyl film layer 11) adjacent and opposite to a side of the resilient sheet to be placed against the skin comprises a substance which does not form strong bond with a wound sealing adhesive used to seal the wound. The applicant has disclosed in the specification that vinyl has this property.

12. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by EP Patent Application 0028452 A1 ("Sanderson").

As regards claim 11, Sanderson discloses an adhesive skin closure device and method of closing/sealing a wound, comprising providing a flexible adhesive skin closure constructed from resilient polyurethane (col. 7, lines 15-16) having openings therein. The skin closure approximates the wound, thereby being wound approximation device. During use, the device is placed under tension and applied by light pressure to the user in order adhere the device via pressure sensitive adhesive to opposite sides of the wound to close the wound. The device is released and the wound is approximated.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3761

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. in view of U.S. Patent No. 3,971,766 ("Ono et al.").

As regards claim 9, Martin et al. fail to teach the type of materials used in constructing the pressure sensitive adhesive. However, Ono et al. disclose a surgical drape having a pressure sensitive adhesive in which butyl acrylate is one of a plethora of alkyl acrylates that may be used in creating the adhesive (col. 2, line 36).

It would have been obvious to one having ordinary skill in the art to modify Martin et al. by substituting the disclosed pressure sensitive adhesive for the pressure sensitive adhesive comprising butyl acrylate as an obvious design choice since Ono et al. teach that this type of pressure sensitive adhesive is for use on surgical drapes.

16. Claims 11-15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,410,818 ("Oyaski") in view of Sanderson.

17. As regards claim 11, Oyaski discloses a method for sealing a wound comprising providing a wound approximation device, which comprises an adhesive member (15) and an opening (40), applying the device to the user inherently under tension, thereby

Art Unit: 3761

inherently increasing the size of the opening in order to draw the opposing sides of the wound together, and pressing the device under tension against the skin to form a bond with the skin, such that the opening exposes a margin of the skin surrounding the wound and releasing the tension of the member, whereby the wound is approximated.

Oyaski fails to teach the member is resilient. Sanderson, however, teaches that it is conventional in the art to construct wound closure devices from resilient material in order to allow the device to be placed on the skin under tension to close a wound.

It would have been obvious to one having ordinary skill in the art to modify Oyaski by constructing the member from a resilient material in order to allow the device to be placed on the skin under tension to close a wound.

As regards claims 12-14, both Oyaski and Sanderson fail to teach debriding the wound, irrigating the wound and disinfecting the wound. However, the examiner contends that these steps are *prima facie* obvious to any wound closure method in order to create a clean environment prior to sealing the wound.

As regards claims 15 and 18, Oyaski discloses sealing the wound with an adhesive.

As regards claim 19, the member of Oyaski is removed after the adhesive is allowed to dry and after the wound has been approximated (col. 2, lines 58-63).

As regards claim 20, Oyaski fails to teach the member is constructed from a urethane sheet and that the adhesive is a cyanoacrylate adhesive. As to the urethane sheet, Sanderson discloses the use of a urethane resilient sheet material. Once modified, Oyaski would also include the urethane sheet material

Art Unit: 3761

As to the adhesive, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to use any suitable wound skin sealing adhesive such as, for example, cyanoacrylate, to seal the wound.

18. Claims 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Sanderson in view of Oyaski.

As regards claim 16 and 17, Sanderson fails to teach suturing or stapling the wound after approximation. Oyaski, however, teaches that it is conventional to include in wound closure methods the step of applying a secondary wound means on a wound having been approximated in order to ensure that the wound remains closed during healing.


In view of Oyaski, it would have been obvious to one having ordinary skill in the art to modify the method disclosed by Sanderson to include a secondary means of holding the wound together (e.g. stapling, gluing, suturing) to ensure that the wound stays closed until it is healed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Monday to Wednesday from 5:30 am to 4:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3761

Kml
March 21, 2004